In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-2020V UNPUBLISHED

ALICE RIVAS,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: September 22, 2023

Special Processing Unit (SPU); Ruling on the Record; Findings of Fact; Influenza ("Flu"); Shoulder Injury Related to Vaccine Administration (SIRVA);

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.

Jennifer Shah, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW ON TABLE CLAIM 1

On December 19, 2019, Alice Rivas ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.² (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA"), as defined by the Vaccine Injury Table, caused by an influenza ("flu") vaccine administered on January 24, 2018. Petition at 1-2. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons described below, I find that Petitioner's injury does not meet the definition of a Table Injury, and therefore that claim must be dismissed.

I. Relevant Procedural History

After the claim's initiation, Respondent filed a Rule 4(c) Report opposing compensation. Respondent's Rule 4(c) Report (ECF No. 34) at 10-13. Petitioner filed a

¹ In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

motion for a ruling on the record with regard to entitlement on August 11, 2022. Motion for Ruling on the Record ("Mot."), ECF No. 39. Petitioner argues that she meets the Table requirements for a SIRVA. Mot. at 4.

Respondent filed a response on October 3, 2022, arguing that Petitioner has not established that onset of her injury occurred within forty-eight hours of her vaccination, that pain was not limited to her left shoulder, or that there is an alternative cause for her symptoms other than the vaccination. Respondent's Response to Motion for Ruling on the Record ("Opp."), ECF No. 40, at 7-9.

II. Petitioner's Medical Records

Petitioner received a flu vaccine in her left shoulder on January 24, 2018. Ex. 15 at 1. There is no history of prior left shoulder pain or issues.³

On February 9, 2018, Petitioner presented to nurse practitioner ("NP") Nicole Gamache for a cough and congestions. Ex. 2 at 1. Petitioner reported that her arm became swollen and bruised after her flu vaccine. Further, she developed a headache, body aches, fever, congestion, and coughing two days after the vaccination. *Id.* Petitioner did not complain of shoulder pain and no musculoskeletal or neurological exam occurred. She was diagnosed with bronchitis and prescribed antibiotics. *Id.* at 2.

Petitioner saw NP Nicholas Kim on March 10, 2018, with complaints of swollen arms and lymph nodes since receiving her flu vaccine, and swelling in her neck, shoulders, and both arms. Ex. 2 at 3-4. An examination showed she had full range of motion and strength. *Id.* at 4. Petitioner was diagnosed with cellulitis and prescribed Keflex. *Id.*

On April 3, 2018, Petitioner saw physician's assistant ("PA") Leslie Ogilvy for a reaction to a flu shot which "includes swelling in left arm and left side neck that did radiate to the right shoulder and upper back." Ex. 1 at 1. She also reported weakness, swelling, and tingling in her left arm and elbow. Ex. 1 at 1. An examination showed full, but painful, range of motion, swelling, and tenderness. *Id.* at 3. Petitioner was diagnosed with swelling and a vaccine reaction. *Id.* at 2.

Petitioner next presented to PA Robert Crandall for a worker's compensation evaluation due to left arm swelling and continued pain on April 10, 2018. Ex. 24 at 10-11. Petitioner reported that "she had significant pain the following day" after her flu vaccine, and that she developed swelling and redness which extended to her neck, right shoulder,

2

³ Petitioner reported that she had a "strong immune reaction" to a flu vaccine in 1976 that resulted in cervical and shoulder muscle spasms. Ex. 1 at 7.

and right upper arm. *Id.* at 10. Since the injection, she reported "intermittent pain and swelling in [her] left shoulder and upper arm." *Id.* at 11. PA Crandall's examination of petitioner's left shoulder and neck revealed a full range of motion with no swelling, bruising, or redness. *Id.* at 11. There was, however, tenderness over the lateral aspect of petitioner's left shoulder and distal biceps, tendon, and upper traps. *Id.*

Petitioner presented to Dr. Cynthia Schafer, and orthopedist, on April 19, 2018, for arm pain "after getting flu shot". Ex. 24 at 2. She reported that she was "still having a lot of pain, feels like there is something in her arm near her elbow, and pain in both shoulders and neck." *Id.* 2. Further, Petitioner stated that "[s]he had significant pain and swelling of [her] shoulder and upper arm into her neck starting in the middle of the night after the [flu] injection." *Id.* at 3. On exam, Petitioner exhibited normal range of motion in her shoulder but tenderness in her left bicep and decreased cervical range of motion. *Id.* at 4. Dr. Shafer noted that Petitioner's cellulitis diagnoses was likely unrelated, and that she did not have a workers compensation injury. *Id.*

Petitioner again complained of pain on April 30, 2018, to Dr. Richard Evans. Ex. 1 at 7. She stated that a flu shot she had received had resulted in painful swelling over a one to two-day period that spread bilaterally to her neck and both shoulders. *Id.* Dr. Evans stated that Petitioner likely had a strong immune reaction. *Id.*

On May 15th, 16th, and 25th, Petitioner saw her primary care provider due to reports of swelling and pain in her arms, right knee, neck, upper back, difficulty breathing, headaches, and anxiety. Ex. 1 at 41-58. Her examinations were normal, and her physician commented that her symptoms may be due to severe anxiety. *Id.* at 46.

On June 1, 2018, Petitioner saw Dr. Laurance Adams, a neurologist, with complaints of bilateral shoulder swelling, neck swelling, numbness in her arms and legs, left arm weakness, and other symptoms. Ex. 4 at 16. Muscle tightness and tenderness was noted in her left side, but her neurological exam was otherwise normal. *Id.* at 17. Dr. Adams assessed a postvaccination autoimmune syndrome with brachial plexitis suspected. *Id.* However, he also noted Petitioner exhibited significant anxiety.

Throughout 2018 and 2019, Petitioner continued to complain of various ailments that she attributed to the flu vaccine, including pain in the neck and shoulders, episodes of nearly passing out, rash, dry mouth, dizziness, double vision, bilateral shoulder pain radiating to neck and biceps, and anaphylaxis. See, e.g., Ex. 4 at 27 (July 18, 2018 neurology visit complaining of pain in neck and shoulders and episodes of nearly passing out); Ex. 5 at 1 (July 25, 2018 visit for rash on buttocks and legs occurring after she received her flu vaccination and acupuncture); Ex. 6 at 4 (August 21, 2018 visit for dry

mouth, dry eyes, dry nose, dizziness, double vision, and difficulty swallowing that began after her flu vaccination and suspected as an autoimmune ailment); Ex. 1 at 148 (October 30, 2018 visit for bilateral shoulder pain radiating to the neck and biceps); *id.* at 157 (December 3, 2018 visit bilateral shoulder and neck pain that radiated to the left shoulder blade, and numbness in her arms and legs); Ex. 19 at 31 (January 7, 2019 pain clinic visit for chronic neck and shoulder pain beginning after flu vaccination; petitioner claimed she went into anaphylaxis within eight hours of the vaccination and was hospitalized (such an episode is not reflected in the records)); Ex. 21 at 35 (July 27, 2019 ER visit for dizziness and weakness; petitioner reported she had been sick ever since her flu vaccination). She was, at various times, assessed with Parsonage Turner Syndrome, radiculopathy, muscle tightness, neuralgic amyotrophy, cervicalgia, and Sjogren's syndrome. See, e.g., Ex. 1 at 148; Ex. 4 at 34; Ex. 6 at 4; Ex. 8 at 15, 37; Ex. 17 at 63; Ex. 19 at 33.

III. Fact Findings and Ruling on Entitlement

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,⁴ a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

(i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

4

⁴ In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See § 11(c)(1)(A)(B)(D)(E).

- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.*

Medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A. Factual Findings Regarding a Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner has not satisfied all of the QAI requirements for a Table SIRVA.

1. Petitioner Had No Prior Left Shoulder Condition or Injury

The first requirement for a Table SIRVA is a lack of problems associated with the affected shoulder prior to vaccination that would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Respondent does not dispute that Petitioner meets this criterion, and I find that she has demonstrated a lack of history of pain, inflammation, or dysfunction of her left shoulder that would explain her symptoms.

2. Pain Did Not Occur within Forty-Eight Hours of Petitioner's Vaccination

The medical records do not establish onset of pain close-in-time to vaccination. Petitioner received the flu vaccine on January 24, 2018. Ex. 15 at 1. She first sought treatment on February 9, 2018, but only for swelling and bruising. Ex. 2 at 1. It is not until April 3, 2018, sixty-nine days after her vaccination, that Petitioner described any pain or tenderness in her left shoulder. Ex. 1 at 3.

Generally, information contained in contemporaneously created medicals records is considered trustworthy because it is provided close in time to the events in question for the purpose of obtaining medical care. *Cucuras*, 993 F.2d at 1528. Here, multiple medical records created within months of vaccination do not refer to Petitioner's shoulder pain occurring within 48 hours of her vaccination. The earliest records also suggest the initial symptoms of any alleged injury was swelling and bruising, but not pain or reduced range of motion.

Petitioner did later report significant shoulder pain as early as April 10, 2018, that began close-in-time to the vaccination. Ex. 1 at 7. However, such records are directly contradicted by more contemporaneous assertions. These later-created medical records are not sufficient to overcome the earlier description of Petitioner's injury, and the lack therein of any reference to pain or reduced range of motion. Additionally, Petitioner did not consistently report onset within forty-eight hours of the vaccine, but the following day, the middle of the first night, or over a "1-2 day period" after the vaccination. Ex. 1 at 7, Ex. 24 at 2, 10.

Petitioner has failed to provide preponderant evidence that the onset of the left shoulder pain she complained of occurred immediately upon vaccination, as she alleges.

3. Petitioner's Pain was not Limited to her Left Shoulder

Petitioner's pain was not limited to her left shoulder, but was described as including various other areas including her neck, back, and both shoulders. Ex. 1 at 7, Ex. 2 at 1, 3-4; Ex. 24 at 10. Further, when seeking treatment Petitioner consistently described other symptoms including bilateral shoulder pain, rashes, dizziness, neck and bicep pain. See, e.g., Ex. 5 at 1, Ex. 6 at 4, Ex. 1 at 148, Ex. 19 at 31. This QAI is thus also not met.

4. Evidence of Another Condition or Abnormality

Additionally, there is evidence revealing Petitioner suffered from other conditions which could explain her symptoms. At various times, Petitioner's ailments were attributed to severe anxiety (Ex. 1 at 46), an autoimmune or neurological cause (Ex. 4 at 17), neuralgic amyotrophy, bilateral cervical radiculitis cervicalgia. See, e.g., Ex. 8 at 15.

The mere existence of another, possibly contributing, condition or abnormality does not prevent a petitioner from satisfying this Table criteria – especially when the timing and course of the injury is consistent with a Table SIRVA injury. Rather, the relevant inquiry is whether the condition or abnormality "wholly explains [a petitioner's] symptoms independent of vaccination." *Lang v. Sec'y of Health & Hum. Servs.*, No. 17-995, 2020 WL 7873272, at *13 (Fed. Cl. Spec. Mstr. Dec. 11, 2020).

In this case, Petitioner's conditions could explain her symptoms. However, Petitioner did not address the issues raised in Respondent's brief.

Conclusion

Accordingly, for the above stated reasons I find that Petitioner has failed to demonstrate the Table requirements for a SIRVA (42 C.F.R. § 100.3(c)(10)), and hereby dismiss Petitioner's Table claim.

In light of the instant ruling, I will proceed with transferring Petitioner's case out of SPU and will randomly reassign the case to a special master to conduct further proceedings to establish whether Petitioner has demonstrated an off-Table claim.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master